VI. Claims 17, 18, drawn to method to determine retinal disease comprising determining if a polypeptide from a cell or sample contains a mutation in an AIPLI encoding or regulating region, classifiable in class 435, subclass 7.1.

VII. Claims 19 and 20, drawn to a method of producing a cell expressing an AIPL1 mutation comprising transfecting a cell with a polynucleotide sequence having at least one AIPLI mutation, classifiable in class 435, subclass 455.

VIII. Claim 26, drawn to a method of screening compounds to determine effectiveness in counteracting a mutation in the AIPLAI gene of a cell, classifiable in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

Further Restriction

A) In addition each of Groups I-VIII above reads on patentably distinct Groups. Each of the Groups I-VIII is further divided into multiple groups each representing a different mutation (e.g., Ala336112). It is noted that "a wild-type AIPL1 sequence" or "a mutant AIPL1 sequence" is sometimes claimed (e.g., claim 1); applicant must specify, for example, which "wild-type AIPL1 sequence" is the elected invention. The multiple mutations comprises a different sequence core that has no consensus sequence and no unifying structural relationship with the other mutations, as in the Groups I-VIII, and no shared functional property resulting from their respective mutations. Thus a further restriction is applied to each of Groups I-VIII.

If one of Groups I-II or IV-VIII is elected, the elected further restricted Group must result in a composition or method comprising a single specific mutation, i.e., a single, identifiable mutation and/or sequence (as in Val33ins 8 bp (GTGATCTT SEQ ID NO: 82).

If either of Groups I and VIII is elected as a combination or mixture, or if Group III, drawn to a library comprising DNA sequences, each sequence corresponding to a DNA sequence including a mutation selected from the group consisting of SEQ ID Nos. 9-41 and mixtures and combinations thereof, is elected, then applicant is required to select one combination of mutants or SEQ ID Nos and to identify the single combination of sequences by their identifiers. This combination will constitute the elected invention. See MPEP 803.04.

For this response to be complete, applicants should identify the selected mutation (or, mixture/combination of mutations, or if Group Ill is elected, combination of SEQ ID Nos.) and list all of the claims readable upon the elected drug core.

This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each mutation. or combination of mutations (as in the library of Group III) is assumed to be a patentably distinct invention, absent evidence to the contrary.

The Inventions of Groups I-III are directed to related compositions and products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not

obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the library of anti-sense DNA sequences of Group III can be used to select antisense oligonucleotides that inhibit gene expression, which is a different mode of operation, function and effect from the polynucleotide sequences of Group I and the proteins of Group II. The polynucleotide sequences of Group I have a materially different design from the protein of Group II by virtue of their different molecular structures (i.e., polynucleotide versus polypeptide).

The Inventions of Groups IV-VIII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.050). In the instant case, the methods of determining retinal disease using polynucleotides, as in Group IV or by using polypeptides, as in Group VI, is a different function and effect from methods of treating retinal disease as in Group V, producing a cell expressing an AIPL1 mutation, as in Group VII, or screening compounds to determine effectiveness in counteracting a mutation, as in Group VIII. The methods of determining retinal disease using polynucleotides, as in Group IV or by using polypeptides, as in Group VI, have different designs, modes of operation, and function, by virtue of their different molecular structures (polynucleotide versus polypeptide). The methods of treating retinal disease as in Group V, producing a cell expressing an AIPL1 mutation, as in Group VII, or screening compounds to determine effectiveness in counteracting a mutation, as in Group VIII have different designs, modes of operation, function and effect.

The Inventions of Groups I-III and the Invention of Groups VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of screening compounds, as in group VIII, may be practiced with peptide-like molecules as potential effective compounds, which are not anti-sense DNA sequences as in Group III, and are also another materially different product from the polynucleotides or proteins of Groups I and II, respectively.

Inventions of Group I and the inventions of Groups IV and VII are related as product and process of use, provided that the elected further Invention of Group I does not encode a wild-type gene. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products of Group I may be used in order to express antigens for antibody production, which is a different use from the methods of determining retinal disease or producing a cell expressing an AIPLI mutation, as in Groups IV and VII.

The Inventions of Groups I and the Invention of Group VI are directed to related gene variants and methods therefore. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the further restricted polynucleotide of Group I is different in design and function from the polypeptides of the claimed methods of determining, as in Group VI.

The Inventions of Group I and II and the Invention of Group V are related as product and process of use, to the extent that applicant elects a Further Invention from the Inventions of Groups I and II, wherein the further Invention is the wild-type gene or gene product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods of treatment of Group V may be practiced with peptide-like molecules, which are not proteins or polynucleotides, as in Groups I or II, and therefore are another materially different product.

The Inventions of Groups I and II and the Invention of Group V are directed to related gene variants and methods therefore, to the extent that applicant elects a Further Invention from the Inventions of Groups I and II, wherein the further Invention is not the wild-type gene or gene product. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the further restricted polynucleotides or polypeptides of Groups I and II are mutants, and so are different in design and function from the wild-type polynucleotides and polypeptides of the claimed methods of treatment, as in Group VI.

Inventions of Group II and the Inventions of Groups IV and VII are directed to related gene variants and methods therefore. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the Invention of Group II and the Inventions of Groups IV and VII are distinct, because the Inventions of Group II are drawn to polypeptides and so have a different design and function from the polynucleotides of Groups IV and VII.

Inventions of Group II and the Invention of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case proteins of Group II may be used to produce antigens

by their inoculation, which is a different function from the method of determining if a polypeptide contains a mutation, as in Group IV.

Inventions of Group III and the Inventions of Groups IV-VII are directed to related gene variants and methods therefor. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the library of anti-sense DNA sequences of Group III, have different modes of operation, function effect from the methods of treatment, determining retinal disease with polynucleotides or polypeptides, or producing cells expressing an AIPL1 mutation, as in the Inventions of Groups IV, V, VI and VII.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

> The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
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> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include

the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

4. This application contains claims directed to the following patentably distinct species: A therapeutic method comprising administering: (a) a protein encoded by a wild type AIPL1 gene; (b) a polynucleotide sequence of a wild type AIPL1 gene or (c) a retinal medication. The species are independent or distinct because they have materially different design, mode of operation, function and effect.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 14 is generic.

5. This application contains claims directed to the following patentably distinct species: A detectable label that is: (a) an enzyme; (b) a radioisotope or (c) a fluorochrome. The species are independent or distinct because they have materially different design, mode of operation, function and effect.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 24 is generic.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants